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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,477	01/16/2004	Dennis M. Laherty	LAH003	7581
27187	7590	11/08/2005	EXAMINER	
BAKER & DANIELS LLP 205 W. JEFFERSON BOULEVARD SUITE 250 SOUTH BEND, IN 46601			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,477	LAHERTY ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/24/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 24, 2004 was filed after the mailing date of the Application on January 16, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Levin (U.S.

Patent No. 3,815,581).

With respect to **Claims 1,2,10,13**: Levin teaches a urinary device 10 for use by a female comprising holding and placement member 14, trough 12 with opposing walls 22 that extend vertically downward from the plane of the trough, that extend in a longitudinal direction as defined by trough 12 to terminate at ends 16 and 18, and define a urine guide channel therebetween. (Fig. 2) (Col. 2, lines 39-47) Levin teaches that placement member 14 is adapted to be gripped by a user (Fig. 7) and held and is designed with curvature 44 (Fig. 2) to conform to the anatomy of the symphysis pubis above the pubic arch. (Col. 3, lines 37-40)

With respect to **Claim 3**: Levin teaches that this device allows a female user to void without the aid of a catheter, however Examiner is concluding that device 10 is capable of serving as a catheter guide as trough 12 is a sufficient means for guiding a catheter between walls 22 and into the vaginal passage 36 via end 16.

With respect to **Claims 4,5,11**: As can best be seen in Figs. 1,2 and 5-9, Levin teaches that the bottom of trough 12 has a curved shape, and Levin also teaches opening 28 (Figs. 1,2) (Col. 3, lines 1,2), which is formed by the point at which curved trough 12 is connected to the placement member 14 and which clearly has a curved shape.

With respect to **Claim 6 and 7**: Levin teaches that the user grips wings 24 to hold placement member 14 against the pubic bone (Fig. 7), and wings 24 are disposed at the upper end of placement member 14. (Fig. 1) Curvature 44 is considered herein to be a "tongue-like projection" on placement member 14.

With respect to **Claim 8,12**: Levin teaches that member 14 extends vertically from trough 12 and lies in a plane substantially perpendicular to the longitudinal axis of trough 12. (Col. 2, 59-61).

With respect to **Claims 9,14**: As can be seen from Figs. 1,2 and 5-9 opposing walls 22 of trough 12 extend in a direction that is substantially transverse to the plane defined by placement member 14 to terminate in end 16 that is inserted into vaginal passage 36. (Col. 4, lines 1,2,3)

Art Unit: 3761

With respect to **Claim 15**: Levin teaches that placement member 14 is formed in one-piece construction with trough 12. (Col. 2, lines 30-32)

With respect to **Claim 16**: Levin teaches that end 16 enters vaginal passage 36 however Examiner is concluding that Applicant considers a vaginal insert to be a separate body that is adapted for placement closer to a user's vagina.

With respect to **Claim 17**: Please see the rejection of Claim 1 as Claim 17 is rejected for all of the same reasons as stated with respect to Claim 1 in addition to the following: End 16 of trough 12 is capable of accommodating a catheter for insertion of a catheter for introduction into vaginal passageway 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin ('581).

With respect to **Claims 18, 20 and 21**: Levin teaches the following regarding operation of device 10 (Col. 4, lines 1-18):

In operation, as shown in FIGS. 7, 8 and 9, device 10 is partially inserted internal to the body with rear end 16 extending into the vaginal passage 36. Insertion continues until arch 26 and opening 28 contact interface with the urethral opening. The patient then holds device 10 in the proper position with the index and middle fingers of one hand as shown. The combination pubic-vaginal curvature 30 and vaginal-perineal curvature 31 of trough 12 separates the anterior vaginal wall 48 and posterior vaginal wall 46. Concurrently, wings 24 in the manner previously described separate the labia transversely. Urine passing from the urethral opening through opening 28 impinges on frontal end 18 of trough 12 and is carried within the urine guide channel to spout 20. The patient may void in either a sitting or standing position and collect the urine specimen in a suitable container that may be held in the other hand.

Although Levin does not explicitly teach insertion of a catheter through end 16 of trough 12, Levin does teach the use of device 10 in tandem with a urine collection device placed adjacent said device 10 and that device 10 is a guide itself for urine management, and given that the shape of trough 12 and the structure of the device as a whole is capable of accommodating a catheter for guiding and placement as stated herein with respect to Claim 3, Examiner is concluding that it would be obvious to one of ordinary skill in the art to use device 10 as a catheter guiding device and thus it would also be obvious to one of ordinary skill in the art to insert a catheter into vaginal passageway 36 via end 16.

With respect to **Claim 19**: Please see the rejection of Claim 19; Examiner is concluding that Levin teaches that device 10 is void of a vaginal insert.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

